HOUSE _____ AMENDMENT NO.___

Offered By

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AMEND House Committee Substitute for House Bill No. 1332, Section 338.600, Page 3, Line 61 by inserting after all of said line the following:

"Section 1. 1. As used in sections 1 to 3, the following words and phrases shall mean:

(1) "Generic alternative", another drug within the same drug class as the originally prescribed medication;

(2) "Generic equivalent", another drug with the same chemical compound as the originally prescribed medication;

(3) "Health carrier", the same meaning as such term is defined in section 376.1350, RSMo;

(4) "Pharmacy benefit manager" or "PBM", a person or entity other than a pharmacy or pharmacist acting as an administrator in connection with pharmacy benefits;

(5) "Switch communication", a communication from a health insurance carrier or PBM to a patient or the patient's physician that recommends a patient's medication be switched by the original prescribing health care professional to a different medication than the medication originally prescribed by the prescribing health care professional.

2. (1) Any time a patient's medication is recommended to be switched to a medication other than that originally prescribed by the prescribing health care professional, a switch communication shall be sent to:

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(a) The patient providing information about why the switch is proposed and the patient's rights for refusing the recommended change in treatment; and

(b) The plan sponsor informing such sponsor of the cost, shown in currency form, of the recommended medication and the cost, shown in currency form, of the originally prescribed medication.

(2) A switch communication shall not be required for generic equivalent medication switches, unless the cost to the patient or plan sponsor is greater than the medication originally prescribed and dispensed.

(3) A switch communication shall be required for generic alternative medication switches.

3. Such switch communication shall:

(1) Clearly identify the originally prescribed medication and the medication to which it has been proposed that the patient should be switched;

(2) Explain any financial incentives that may be provided to, or have been offered to, the prescribing health care professional by the health carrier of PBM that could result in the switch to the different drug. In particular, cash or in-kind compensation payable to prescribers or their professional practices for switching patients from their currently prescribed medication to a different medication shall be disclosed to the patient as well as incentives that may be provided through general health care professional compensation programs used by the health carrier or PBM;

(3) Explain any financial incentive that a health carrier or PBM may have to encourage the switch to a different drug;

(4) Advise the patient of his or her rights to discuss the proposed change in treatment before such a switch takes place, including a discussion with the patient's prescribing health care professional, the filing of a grievance with the health carrier to prevent the switch if such a switch is based on a financial incentive and the filing of a grievance with the department of insurance, financial institutions, and professional registration; and

(5) Explain any cost sharing changes for which the patient is responsible.

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4. Switch communications to health care providers shall disclose financial incentives or benefits that may be received by the health carrier or PBM.

5. Switch communications to health care providers shall direct the prescriber to advise the patient that is subjected to a switch by the prescriber of any financial incentives received by the prescriber or other inducements from the health carrier or PBM that may influence the decision to switch.

6. A copy of any switch communication sent to a patient shall also be sent to the prescribing health care professional.

7. Health insurance payers, including employers, shall be notified of medication switches among plan participants. Such notification shall include any financial incentive the health carrier or PBM may be utilizing to encourage or induce the switch. Information contained in the notification shall be in the aggregate and must not contain any personally identifiable information.

8. The department of insurance, financial institutions, and professional registration shall create one form for health carriers and pharmacy benefit managers to use in switch communications to patients, prescribing health care professionals, and health insurance payers including employers.

9. The department shall promulgate rules governing switch communications.

10. Such rules shall include, but not be limited to the following:

(1) Procedures for verifying the accuracy of any switch communications from health benefit plans and pharmacy benefit managers to ensure that such switch communications are truthful, accurate, and not misleading based on cost to the patient and plan sponsor, the product package labeling, medical compendia recognized by the MO HealthNet program for the drug utilization review program, and peer-reviewed medical literature, with appropriate referenced provided;

(2) A requirement that all switch communications bear a prominent legend on the first page that states: "This is not a product safety notice. This is a promotional announcement from your health care insurer or pharmacy benefit manager about one of your current prescribed medications.";

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(3) A requirement that, if the switch communication contains information regarding a potential therapeutic substitution, such communication shall explain that medications in the same therapeutic class are associated with different risks and benefits and may work differently in different patients.

11. Any rule or portion of a rule, as that term is defined in section 536.010, RSMo, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536, RSMo, and, if applicable, section 536.028, RSMo. This section and chapter 536, RSMo, are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536, RSMo, to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2008, shall be invalid and void.

Section 2. 1. Issuing or delivering or causing to be issued or delivered a switch communication that has not been approved and is not in compliance with the requirements of section 1 is punishable by a fine not to exceed twenty-five thousand dollars.

2. Providing a misrepresentation or false statement in a switch communication under section 1 is punishable by a fine not to exceed twenty-five thousand dollars.

3. Any other material violation of section 1 is punishable by a fine not to exceed twenty-five thousand dollars.

Section 3. 1. When medications for the treatment of any medical condition are restricted for use by a health carrier or PBM by a step therapy or fail first protocol, a prescriber may override such restriction if:

(1) The preferred treatment by the health carrier or the PBM has been ineffective in the treatment of the covered person's disease or medical condition; or

(2) Based on sound clinical evidence and medical and scientific evidence:

(a) The preferred treatment is expected to be ineffective based on the known relevant physical or mental characteristics of the covered person and known characteristics of the drug

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regimen, and is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance; or

(b) The preferred treatment has caused or based on sound clinical evidence and medical and scientific evidence is likely to cause an adverse reaction or other harm to the covered person.

2. The duration of any step therapy or fail first protocol shall not be longer than a period of fourteen days.

3. For medications with no generic equivalent and for which the prescribing physician in their clinical judgment feels that no appropriate therapeutic alternative is available a health carrier or PBM shall provide access to United States Food and Drug Administration (FDA) labeled medications without restriction to treat such medical conditions for which an FDA labeled medication is available."; and

Further amend said bill by amending the title, enacting clause, and intersectional references accordingly.

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